

Draft Guidance for Industry
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products
Chemistry, Manufacturing, and Controls Documentation

Docket No. 99D-1454, CDER 98185, June 2, 1999
Page 29657 [FR Doc. 99-13921]

Lines 497 - 500: SPRAY PATTERN

497 The spray pattern should be determined, preferably by a procedure specific for the drug
498 substance, at different distances (e.g., two) from the nosepiece to provide greater
499 discriminatory capability to the test. 500

A single optimal distance should be sufficient to determine the quality of spray pattern of the nasal spray pump for routine quality control.

Internal studies have shown that whilst the general spray pattern shape becomes more pronounced the greater the distance, it becomes more and more difficult to differentiate between the umbral and penumbral parts of the spray pattern. In addition, since most of the nasal spray is deposited in the anterior and turbinate regions which has been shown to be a distance of between 0 cm to 8 cm*, the determination of the spray pattern at a distance further than approximately 8 cm is not representative of in-vivo use of the nasal spray pump.

In conclusion, we believe that a second distance provides no added value to the spray pattern test at the packaging quality control level. Please refer our drug master file 12525 submission of June 1999 (pages 740-755) for supporting data (please note that the DMF is confidential and is for FDA review only).

* Reference: 'Drug Delivery to the Lungs, 1998, *Deposition Pattern of a Nasal Spray in the Human Nasal Airway*', Cheng Y.S., Holmes, T.D., and Guilmette, R.A. (see ANNEX 1)

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Comments by Valois SA - Nasal Spray Pump/Packaging Supplier

August 27th, 1999